GAO

Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

DOCUMENT FOR PUBLIC RELEASE
The decision issued on the date below was subject to a GAO Protective Order. This redacted version has been approved for public release.

Decision

Matter of: Bristol-Myers Squibb Company

File: B-281681.12; B-281681.13

Date: December 16, 1999

Alex D. Tomaszczuk, Esq., Devon E. Hewitt, Esq., Edward C. Schweitzer, Jr., Esq., and Dennis Pryba II, Esq., Shaw Pittman, for the protester.
Benjamin N. Thompson, Esq., Jennifer E. McDougal, Esq., and Grady L. Shields, Esq., Wyrick Robbins Yates & Ponton, for Bayer Corporation, an intervenor.
J. Albert Calluso, Esq., John P. Patkus, Esq., and Sharif T. Dawson, Esq., Defense Logistics Agency, for the agency.
David A. Ashen, Esq., and John M. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Although flaw in agency's proposal scoring methodology could have unreasonably exaggerated the significance of minimal differences among proposals, protest challenging the methodology is denied where the scoring in fact reflected the awardee's proposal's significant advantage.

DECISION

Bristol-Myers Squibb Company (BMS) protests the award of a contract to the Bayer Corporation under phase II of the procurement under request for proposals (RFP) No. SP0200-99-R-1502, issued by the Defense Supply Center Philadelphia (DSCP), Defense Logistics Agency, for HMG-CoA Reductase Inhibitors. BMS asserts that the evaluation of proposals was inconsistent with the terms of the solicitation and otherwise unreasonable.

We deny the protest.

The solicitation, issued on October 23, 1998, contemplated the award of one or two fixed-price national contracts, for an 18-month base period with 2 option years, for an estimated annual quantity of 65 million HMG-CoA Reductase Inhibitors (cholesterol-lowering drugs, commonly referred to as statins), for use in the Department of Defense's (DOD) formulary programs and military treatment

facilities. One contract was to be awarded under phase I for either atorvastatin or simvastatin; a second contract was to be awarded under phase II in the event that the addition of a second statin would yield a lower cost-efficacy ratio than would a single award. Amend. No. 0002 at 27. In this regard, the solicitation provided that "[t]he cost-efficacy of a potential second statin is calculated in conjunction with the initially-selected statin (atorvastatin or simvastatin). The cost-efficacy for the formulary combination of the two statins is then compared to the cost-efficacy of the initially-selected statin and to other statins combined with the initially-selected statin." Id. at 34. The solicitation provided for calculation of the cost-efficacy of any particular statin through a mathematical formula that considers both the drug's annual cost per patient and the efficacy of the statin in lowering low-density lipoprotein cholesterol (LDL-C). RFP at 31.

As amended, the solicitation provided that proposals would be evaluated based on the following three factors (listed in descending order of importance): cost-efficacy, evidence of effect on incidence of fatal and non-fatal myocardial infarctions, and past performance. (In the event that proposals were rated essentially equal after application of these factors, the solicitation provided for consideration of the inconvenience of switching patients to the contracted statins.) Amend. No. 0002 at 29, 34; Amend. No. 0006. Under the evaluation plan, a maximum of four evaluation points were available for cost-efficacy, three for evidence of effect on incidence of fatal and non-fatal myocardial infarctions, and two for past performance. With respect to cost, the RFP provided in an addendum to Standard Form 1449 (Solicitation/Contract/Order for Commercial Items) that "[f]ailure of an offeror to submit a 'Per Tablet/Capsule' price on all of its commercially available: (i) strengths . . . may preclude the offeror from being considered for an award." RFP at 8; Amend. No. 0010.

BMS, Bayer and three other offerors submitted proposals by the closing time for receipt of proposals. On May 12, DSCP issued its first request for final proposal revisions (FPR) to all five offerors. On June 10, after concluding that the final proposals submitted by two of the offerors contained deficiencies that precluded award to them, DSCP requested a second round of FPRs. Based upon its evaluation of the second FPRs, DSCP determined that Merck & Company's proposal, for simvastatin, was the most advantageous phase I offer. DSCP then compared the cost-efficacy of Merck's simvastatin alone with the combination of simvastatin and the other statins; the agency determined that the combination of simvastatin and cerivastatin, offered by Bayer, offered the lowest cost-efficacy ratio and that a phase II award to Bayer was most advantageous. In this regard, Bayer's proposal received five points, the highest phase II score, including: four points under the cost-efficacy factor because its cost-efficacy ratio ($[DELETED]) was evaluated as substantially lower than any other offeror's, including BMS's ($[DELETED]); zero points under the factor for evidence of effect on incidence of fatal and non-fatal myocardial infarctions because no studies showed that Bayer's recently approved statin reduced the incidence of fatal or non-fatal cardiovascular events; and one point for acceptable past performance. In contrast, BMS's proposal received four

points, including zero points under the cost-efficacy factor, three points under the factor for evidence of effect on incidence of fatal and non-fatal myocardial infarctions, and one point for acceptable past performance. Upon learning of the resulting award to Bayer, and after receiving a debriefing from DSCP, BMS filed this protest with our Office challenging the phase II award to Bayer.

COST-EFFICACY

Scoring Methodology

BMS asserts that the scoring under the cost-efficacy factor was unreasonable and inconsistent with the solicitation. As noted above, under the source selection plan, a maximum of four (out of a total of nine) evaluation points were available for cost-efficacy. In this regard, the agency's evaluation plan provided that four points would be awarded in the event that a proposed statin's "[c]ost-efficacy ratio is substantially lower than the cost-efficacy ratio of the other statin"; one point would be awarded in the event that a proposed statin's "[c]ost-efficacy ratio is slightly lower than the cost-efficacy ratio of the other statin"; and no points would be awarded in the event that a proposed statin's "[c]ost-efficacy ratio is the same or higher than the cost-efficacy ratio of the other statin." Revised Statin Evaluation Plan, Statin Evaluation Score Sheet.

An addendum to the evaluation plan defined when a proposed statin's cost-efficacy ratio would be viewed as substantially (rather than slightly) lower than the cost-efficacy ratio of the other statin. Specifically, a sensitivity analysis was to be performed in which the percentage of LDL-C reduction for the statin with the higher cost-efficacy ratio would be increased by 1 percent at each dosage. If the statin that had the lowest cost-efficacy ratio in the base calculation still had the lowest cost-efficacy ratio, then that statin's cost-efficacy ratio was to be considered substantially lower than the cost-efficacy ratio for the other statin and four points were to be awarded for the statin with the lower cost-efficacy ratio. If the statin that had the lowest cost-efficacy ratio in the base calculation no longer had the lowest cost-efficacy ratio after the sensitivity analysis, then that statin's cost-efficacy ratio was to be considered only slightly lower than the cost-efficacy ratio for the other statin and only one point was to be awarded. Revised Statin Evaluation Plan, Addendum.

BMS argues that this was a purely mechanical scoring approach that unreasonably exaggerated the differences in cost-efficacy ratios, resulting in its proposal receiving zero points compared to Bayer's four points under this factor. The protester notes that even a one-point change in this four-point difference would result in a tied score for Bayer and BMS, and contends that, in that event, BMS would be in line for award under the solicitations tie-breaker clause (i.e., in the event that proposals were rated essentially equal, the inconvenience of switching patients to the contracted statins would be considered).

As a preliminary matter, DSCP asserts that BMS's protest in this regard is untimely. Specifically, DSCP notes that (1) on March 24, 1999, after receipt of initial proposals and prior to receipt of the initial FPRs, counsel for BMS was furnished with a copy of the revised internal evaluation plan, including the Statin Evaluation Score Sheet (but not the Addendum), under a protective order issued by our Office in connection with several protests against the terms of the solicitation, and (2) on or about August 13, after second FPRs and before award, counsel for BMS was furnished (under the protective order) with a copy of the latest version of the revised evaluation plan, which included the Addendum defining when the cost-efficacy ratio of one statin would be viewed as substantially rather than slightly lower than the cost-efficacy ratio of the other statin. According to the agency, BMS was required by our Bid Protest Regulations, 4 C.F.R. § 21.2(a)(2) (1999), to file any protest of the agency's intended evaluation approach in this regard not later than 10 days after receipt of the Revised Statin Evaluation Plan in March or of the Addendum on or about August 13. Since BMS's protest in this regard was not filed until September 7, DSCP asserts, the protest should be dismissed as untimely.

We disagree. DSCP's argument is based on BMS's knowledge (through its counsel) of the agency's internal evaluation plan. However, we are not persuaded that the evaluation plan constituted adequate notice of the protest ground. It is well-established that an assertion that an agency failed to follow its source selection plan does not state a valid basis for protest, since a source selection plan only provides internal agency guidance and does not establish legal rights and responsibilities such that actions taken contrary to it are subject to objection. Microcosm, Inc., B-277326 et al., Sept. 30, 1997, 97-2 CPD ¶ 133 at 12; Indian Resources Int'l, Inc., B-256671, July 18, 1994, 94-2 CPD ¶ 29 at 3. Since an agency is not required to follow its source selection plan, knowledge of the contents of the plan constitutes notice only as to what the agency may do in the future. Protests against future possible agency action are premature and we will not consider them. See Saturn Indus.--Recon., B-261954.4, July 19, 1996, 96-2 CPD ¶ 25 at 5. It follows that we do not believe a protester is required to file a protest, prior to the source selection, based on its knowledge of the terms of a source selection plan. Further, once award is made to another offeror, the protester need not (and indeed may not) file its protest until after, as here, it receives its requested and required debriefing and learns the basis for the award. 4 C.F.R. § 21.2(a)(2). Thus, BMS's post-award protest of DSCP's cost-efficacy scoring is timely.

Our Office will question an agency's evaluation of proposals only if it lacks a reasonable basis or is inconsistent with applicable statute or regulation or with the stated evaluation criteria for award. Cobra Techs., Inc., B-280475 et al., Oct. 6, 1998, 98-2 CPD ¶ 98 at 3; DAE Corp., Ltd., B-257185, Sept. 6, 1994, 94-2 CPD ¶ 95 at 4.

Here, the solicitation indicated that cost-efficacy was the most important evaluation factor. The RFP gave no indication that one offeror could receive zero points under the most important evaluation factor and another as many as four (out of nine available points for the overall evaluation) based on minimal differences in the

cost-efficacy factor. Such a result, however, was possible under the agency's scoring approach. For example, the sensitivity analysis performed here, increasing the percentage of cholesterol reduction for BMS's statin by 1 percent at each dosage level, decreased BMS's cost-efficacy ratio from $[DELETED]to $[DELETED]; had this minimal change (of $[DELETED], or less than 5 percent) displaced Bayer's cost-efficacy ratio ($[DELETED]) as the low ratio, Bayer's cost-efficacy factor would have been evaluated as only slightly lower and its proposal would have received only one point under the cost-efficacy factor rather than the four points it received. Such a dramatic result from such a small change suggests that this mechanical scoring approach was flawed in that it was not designed to reasonably reflect incremental differences in pricing or effectiveness; rather, the agency's methodology could exaggerate the significance of minimal differences among offerors' cost-efficacy ratios, contrary to what offerors could reasonably assume under the stated evaluation approach. Frank E. Basil, Inc., B-238354, May 22, 1990, 90-1 CPD ¶ 492 at 3; SIMCO, Inc., B-229964, Apr. 19, 1988, 88-1 CPD ¶ 383 at 4; National Capital Med. Found., Inc., B-215303.5, June 4, 1985, 85-1 CPD ¶ 637 at 11-12.

The foregoing notwithstanding, we will not sustain a protest unless the protester demonstrates a reasonable possibility that it was prejudiced by the agency's actions. McDonald-Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; see Statistica, Inc. v. Christopher, 102 F.3d 1577, 1581 (Fed. Cir. 1996). Here, the record indicates that, as applied to the evaluation of Bayer's and BMS's proposals under the cost-efficacy factor, the flaw in the agency's scoring methodology did not prejudice BMS. Specifically, BMS's basic cost-efficacy ratio ($[DELETED]) was significantly higher (approximately 29 percent) than Bayer's ($[DELETED]). Bayer's superiority in this regard reflected the fact that: (1) Bayer's evaluated price was significantly lower than BMS's—the evaluated average price of each of Bayer's dosages (.2 mg., .3 mg., and .4 mg.) was $[DELETED], while the evaluated average price of BMS's 10 mg., 20 mg., and 40 mg. dosages was $[DELETED], $[DELETED], and $[DELETED] respectively; and (2) the effectiveness of Bayer's statin tended to be higher than that of BMS's statin, with an evaluated [DELETED] percent, [DELETED] percent and [DELETED] percent LDL-C reduction for Bayer's .2 mg., .3 mg. and .4 mg. dosages respectively, versus an evaluated [DELETED] percent, [DELETED] percent, and [DELETED] percent LDL-C reduction for BMS's 10 mg., 20 mg. and 40 mg. dosages respectively. In response to the protest, the agency's source selection authority maintains that, given the significance of the difference in the cost-efficacy ratios, any flaw in the scoring methodology simply does not come into play--Bayer's proposal was entitled to a four-point advantage under the cost-efficacy factor even using a scoring approach designed to more closely reflect incremental differences in the cost-efficacy ratios.

We find no basis to object to the agency's determination that Bayer was entitled to a four-point advantage under the cost-efficacy factor. While we believe that there is a potential inherent in DSCP's methodology for minor differences in cost-efficacy ratios to lead unpredictably to vastly disparate evaluation scores, we are persuaded that Bayer's higher score here reflected an actual, significant advantage with respect

to the cost-efficacy ratios; there is no basis to conclude that the relative scores received under this factor were unreasonable or inconsistent with the stated evaluation scheme. Accordingly, we think that DSCP's scoring approach operated to fairly reflect the difference between Bayer's and BMS's cost-efficacy ratios in this procurement. In other words, BMS was not competitively prejudiced by the flawed approach.[1]

Dosages Evaluated

BMS argues that, in calculating the cost-efficacy ratio in the event of a phase II award to BMS in conjunction with the phase I award to Merck, the agency unreasonably included in the calculation all three dosages--10 mg., 20 mg., and 40 mg.--of BMS's statin (pravastatin). According to the protester, given the relative effectiveness and price of dosages, the 20 mg. and 40 mg. dosages of its statin should have been excluded from the cost-efficacy calculation, since in practice physicians would likely prescribe the 10 mg. and 20 mg. dosages of Merck's statin (simvastatin), rather than the 20 mg. and 40 mg. dosages of BMS's statin, when making an upward dosage adjustment from the BMS 10 mg. dosage.

This argument is without merit. To the extent that BMS contends that it should have been awarded a contract for only its 10 mg. dosage, DSCP reports that it would be unacceptable to award a contract to BMS for only the lowest dosage because physicians want to "make at least one upward dosage adjustment using the same statin" in the event that a patient does not reach his/her LDL-C reduction goal at the lowest dosage. Contracting Officer's Report at 23-24. To the extent that BMS contends that it should have been awarded a contract for all three dosages but evaluated only on one dosage, we note that offers must be evaluated on the basis of the work actually awarded, see generally Aydin Corp., B-227817, Sept. 28, 1987, 87-2 CPD ¶ 306 at 3, and it would be improper to award a phase II contract to BMS for all three of its dosages when only one was considered in the scoring.[2] We conclude that

---

[1] BMS argues that the 1-percent adjustment used in the sensitivity analysis was insufficient to account for the actual uncertainties in the calculation of statin effectiveness. However, in view of our conclusion that (even absent the sensitivity analysis) the scoring under the cost-efficacy factor reasonably reflected a significant difference between BMS's and Bayer's evaluated cost-efficacy ratios, this argument is academic.

[2] In any case, the record indicates that, even had the agency calculated cost-efficacy on the basis of only BMS's lowest-priced, lowest-strength dosage, the resulting cost-efficacy ratio ($[DELETED]according to DSCP, Contracting Officer's Report at 24 n.6) for a phase II award to BMS still would have been significantly higher than the cost-efficacy ratio ($[DELETED]) for a phase II award to Bayer.

the agency properly considered all dosages of BMS's statin in the cost-efficacy calculation.[3]

PAST PERFORMANCE

BMS challenges the evaluation of past performance, the third most important evaluation factor. In this regard, the solicitation provided under the past performance factor that the government would develop a level of confidence rating, the "most important factor" of which would be the offeror's past performance. The RFP stated that "[t]he Government will evaluate the offeror's reputation for conforming to specifications and to standards of [the Food and Drug Administration (FDA)], adherence to contract schedules . . . , reasonable and cooperative behavior and commitment to customer satisfaction, and for having a business-like concern for the interest of the customer." Amend. No. 0002 at 33. Offerors were required to: (1) list any recalls issued for the proposed statin within the last year; (2) list notices and warnings within the last year concerning failure of the statin or the proposed manufacturing facilities to meet regulations; (3) list pending regulatory actions with respect to the statin or the proposed manufacturing facilities; and (4) "[l]ist five customers with whom your firm has had recent and relevant contracts of comparable size and covering the product group cited in this solicitation," and furnish specified information (including a point of contact) "[f]or each contract." Amend. No. 0003 at 27a. Under DSCP's evaluation plan, two evaluation points (out of the nine total available points) were available for "highly acceptable" past performance, one point for "acceptable" past performance, and zero points for "unacceptable" past performance. Revised Statin Evaluation Plan, Statin Evaluation Score Sheet.

BMS's proposal included information concerning five contracts: a contract with the Department of Veterans Affairs (VA) for the period 1991 to 1998, with approximately $53 million in sales of its proposed statin; a VA contract, with less than $1 million in statin sales for 1998; a DSCP distribution and pricing agreement (DAPA) contract, with approximately $134 million in statin sales for the period 1991 to 1998; a DSCP contract, with less than $1 million in statin sales for the period 1994 to 1998; and a

---

[3] BMS asserted in its initial protest, filed on September 7, that the solicitation was silent--"DSCP did not specify in its Solicitation on what basis the transition to the first statin would take place"--when performing the cost-efficacy calculation. BMS Protest, Sept. 7, 1999, at 16. Then, in its September 21 response to the agency's motion to dismiss the protest, BMS argued for the first time in this protest that DSCP's evaluation approach was inconsistent with a hypothetical cost-efficacy calculation included in the RFP as an example. BMS Comments, Sept. 21, 1999, at 5-6. Since BMS's September 21 argument in this regard was filed more than 10 days after BMS learned, at the September 2 debriefing, of the specifics of the actual cost-efficacy calculation, it is untimely and will not be considered. 4 C.F.R. § 21.2(a)(2).

commercial contract, with approximately $87 million in statin sales. BMS Technical Proposal, attach. 2. DSCP was advised by the VA and DSCP's DAPA administrator that BMS's contract performance was acceptable. Contracting Officer's Report, Oct. 13, 1999, at 37-38. During discussions, Bayer, whose proposed statin had just received FDA approval in June 1997, furnished information concerning one commercial contract, commencing in 1998, with $160,887 in statin sales. Bayer FPR, May 20, 1999. In addition, DSCP was aware that Bayer has two DSCP DAPA contracts for pharmaceutical products, with sales of approximately $13 million in fiscal year 1998, including statin sales of approximately $31,000, and three VA contracts, apparently for pharmaceutical products, with 1998 sales of approximately $20 million under two of the three contracts. DSCP was advised by the VA and DSCP's DAPA administrator that Bayer's contract performance was acceptable. Contracting Officer's Report, Oct. 13, 1999, at 38; DSCP Comments, Nov. 23, 1999. Both BMS and Bayer stated in their proposals that there had been no recalls or regulatory violations, and that there were no pending regulatory actions, with respect to the proposed statin or statin manufacturing facilities. BMS Technical Proposal, attach. 2; Letter from Bayer to DSCP (Dec. 9, 1998).

Although DSCP initially rated BMS's past performance as highly acceptable (warranting a score of 2 points), and Bayer's past performance as only acceptable (warranting a score of 1 point), the contracting officer ultimately concluded that there was no basis for rating any offeror's past performance as more than acceptable. Pre-Negotiation Briefing Memorandum Addendum at 10; Addendum to Pre-Negotiation Briefing Memorandum Addendum; Price-Negotiation Memorandum at 11; Contracting Officer's Report at 38-39.

BMS argues that, based on its successful performance of large government contracts for the proposed statin, and Bayer's lack of performance history with respect to its proposed statin, there was a basis for distinguishing its proposal from Bayer's in this area and rating its past performance as highly acceptable.

BMS's position ignores the fact that, while it does have extensive experience furnishing its proposed statin, the contracting officer reports that its performance on its contracts with the government was rated by the references contacted by DSCP as acceptable. In the absence of any showing by BMS that contracting officials were aware that its recent performance on these contracts was superior, we have no basis to question DSCP's awarding BMS's proposal an acceptable past performance rating, rather than the highest rating. As for Bayer's evaluation, awarding an acceptable past performance rating here--rather than a highly acceptable or unacceptable rating--was consistent with the reports received by DSCP of Bayer's acceptable performance on large government contracts for pharmaceutical products.[4]

[4] BMS argues that DSCP improperly reopened discussions after first FPRs, permitting Bayer to correct deficiencies in its proposal. However, DSCP in fact afforded all offerors an opportunity to submit a revised FPR, and we held in connection with a

(continued...)

Based upon our review of the record, including all of the arguments raised by BMS, we find no basis to object to the award to Bayer.

The protest is denied.

Comptroller General
of the United States

(...continued)
prior protest on this same matter that the reopening of discussions and requesting of second FPRs was unobjectionable. Novartis Pharmaceuticals Corp., B-281681.10, B-281681.11, Aug. 19, 1999, 99-2 CPD ¶ ___ at 6.